Kimberly-Clark Corporation

OCT - 7 2011

Special 510(k) for Kimberly-Clark* U by KOTEX Sleek* Unscented Menstrual Tampons

Section 5. 510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Submitter's Name:	Kimberly-Clark Corporation
Submitter's Address:	2100 Winchester Road Neenah, WI 54956 **Mailing address for regulatory correspondence:** 1400 Holcomb Bridge Road Roswell, GA 30076-2199
Submitter's Phone No:	770-587-8083
Submitter's Fax No.	920-225-3632
Date of Preparation:	September 07, 2011
Name of Device Trade Name: Common Name: Classification Name: Product Code: Classification:	U by KOTEX Sleek* Unscented Menstrual Tampons; Regular, Super and Super Plus absorbencies (Applicators in Black, Purple, Blue, Emerald (green), Coral Orange and Chartreuse (yellow) pearlescent colors) Menstrual Tampon, Unscented Tampon, Menstrual, Unscented HEB 21CFR884.5470
Legally marketed device to which equivalency is claimed:	Kimberly-Clark* U by KOTEX Click* Unscented Menstrual Tampons; Regular, Super and Super Plus absorbencies (Applicators in lime green, pink, blue and yellow pearlescent colors) - K091749
Description of the device:	This device is a conventional unscented menstrual tampon consisting of an absorbent pledget, overwrap, a withdrawal cord and an applicator. The terminology used in describing the device in rest of the 510(k) submission is as follows; ***Complete device:*** U by KOTEX Sleek* Unscented Menstrual Tampons with applicator ***Tampon component:*** Absorbent pledget, overwrap and a withdrawal cord. ***Applicator:*** Inner plunger tube and an outer insertion tube (barrel) formed with a closed, rounded tip with a unique

Special 510(k) for Kimberly-Clark* U by KOTEX Sleek* Unscented Menstrual Tampons

	textured grip. The absorbent pledget consists of a ribbon of rayon fibers. A rayon-polyester blend withdrawal cord is placed on the ribbon and the ribbon is radially wound, then compressed into a traditional eight-groove bullet-shaped pledget, overwrapped with a non-woven fabric. The withdrawal string will be available in pink and white colors. The tampon component is inserted into a two-piece plastic applicator consisting of an inner plunger tube and an outer insertion tube (barrel) formed with a closed, rounded tip. Each tampon with applicator is wrapped in an individual plastic film wrapper and packaged in sealed multi-unit containers for retail sale.
Summary of technological characteristics compared to the predicate device:	Kimberly Clark U by KOTEX Click* Unscented Menstrual Tampons predicate device (K091749) has a compact applicator with an inner plunger tube, a clear middle telescopic tube and an outer insertion tube (barrel) formed with a closed, rounded tip and is presented in lime green, pink, blue and yellow pearlescent colors. The modification in the subject device is in providing a full size applicator with a unique grip and in adding new colorants to the applicator presentations. The modified applicator now has an inner plunger tube and an outer insertion tube (barrel) formed with a closed, rounded tip but does not have the middle telescopic tube and is presented in black, purple, blue, emerald (green), coral orange and chartreuse (yellow) pearlescent colors. There are no significant differences with respect to the other raw materials used in the manufacture of the subject applicators as compared to the predicate device. The fundamental scientific technology and intended use remains exactly the same between the subject and the predicate devices. All performance characteristics, product efficacy and safety considerations between the subject device and the predicate have been shown to be equivalent. The subject device is thus composed of a 100% rayon radially-wound eight-groove bullet-shaped pledget, an overwrap and a withdrawal string and a two piece plastic applicators in black, purple, blue, Emerald (green), coral orange and chartreuse (yellow) pearlescent colors. The withdrawal string will be available in pink and white colors. No changes were made to the tampon component itself. The predicate device is also composed of a 100% rayon radially-wound eight-groove bullet-shaped pledget, an overwrap and a withdrawal string and a three piece

Kimberly-Clark Corporation

Special 510(k) for Kimberly-Clark* U by KOTEX Sleek* Unscented Menstrual Tampons

	telescoping plastic applicator, and the applicators presentations are available in lime green, pink, blue and yellow pearlescent colors.		
Brief description of preclinical testing: biocompatibility and colorant extration tests	**Preclinical Tests** Cytotoxicity Test Mucosal Irritation Test Mucosal Sensitization Test Colorant Extraction test	**Standard** ISO 10993, Part 5 ISO 10993, Part 10 ISO 10993, Part 10 USP 661	**Performance** Meets Meets Meets Meets
Safety Assessment:	The subject 510(k) device has undergone colorant extraction and biocompatibility testing. The results of these studies support the conclusion that the subject 510(k) device is equivalent and as safe as the predicate device, the Kimberly-Clark* U by KOTEX Click* Unscented Menstrual Tampons with applicator.		
Effectiveness:	The subject 510(k) device complies with the Syngyna absorbency requirements of 21 CFR § 801.430 as does the predicate device, the Kimberly-Clark* U by KOTEX Click* Unscented Menstrual Tampons.		
Conclusions:	The results of performance and safety assessments of the subject device support the conclusion that it is safe for its intended use and that it is substantially equivalent to the predicate device, the Kimberly-Clark* U by KOTEX Click* Unscented Menstrual Tampons.		

*Trademark of Kimberly-Clark Worldwide, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Swarna Mukund, Ph.D.
Regulatory Affairs Technical Leader
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
ROSWELL GA 30076

OCT - 7 2011

Re: K112635
Trade/Device Name: Kimberly-Clark* U by KOTEX Sleek* Unscented Menstrual Tampons
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: September 7, 2011
Received: September 9, 2011

Dear Dr. Mukund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Kimberly-Clark Corporation

INDICATIONS FOR USE

Applicant: **Kimberly-Clark Corporation**

510(k) Number: K112635

Device Name: Kimberly-Clark* U by KOTEX Sleek* Unscented Menstrual Tampons

Indications for Use: Kimberly-Clark* U by KOTEX Sleek* is an unscented menstrual tampon inserted into the vagina to absorb menstrual fluid.

Prescription Use_____ OR Over-The-Counter ___X___
Per 21CFR 801.109 Subpart D Per 21CFR 801.109 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112635